DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 8, 2014

EL Global Trade Ltd.
Dr. Shlomit Segman
Quality Assurance and Regulatory Affairs Manager
Tzoran 4th Street
P.O. Box 8242
Netanya, 42504 - Israel

Re: K140381
Trade/Device Name: sensiLight/sensiLight plus
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: June 15, 2014
Received: July 14, 2014

Dear Dr. Segman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Kl40381

Device Name
sensiLight/sensiLight Plus

Indications for Use *(Describe)*
The sensiLight™/sensiLight™ Plus device is an over-the-counter device intended for the removal of unwanted hair. The sensiLight™/sensiLight™ Plus is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.08.07 11:38:18 -04'00'

510(K) SUMMARY FOR EL GLOBAL TRADE LTD.'S SENSILIGHT

DATE PREPARED: FEB 10TH, 2014

1. 510(K) OWNER NAME

EL Global Trade Ltd.
Tzoran 4th st, P.O.Box 8242, Netanya 42504, Israel.
Phone: +972-9-7889069, Fax: +972-9-7734831.

Contact person name: Dr. Shlomit Segman, QA and RA manager
Phone: +972-9-7889069, Fax: +972-9-7734831, E mail: Shlomit@elglobalt.com

2. DEVICE NAME

Common/Usual Name: Light based hair removal deices
Proprietary/Trade name: *sensiLight (sensiLight and sensiLight Plus*)
Classification: EL Global Trade Ltd.'s *sensiLight* device has been classified as **Class II** device under the following classification names:

Classification Name	Product Code	Regulation Number	Panel
Light Based Over-The-Counter Hair Removal	OHT	878.4810	General and Plastic Surgery

3. PREDICATE DEVICES

EL Global Trade Ltd.'s *sensiLight* device is substantially equivalent to the following Predicate Device:

3.1 Home Skinovations Ltd.'s *Glide device,*
cleared under 510(k) number **K131870** at August 14th, 2013.

3.2 Home Skinovations Ltd.'s Silk'n Flash N Go,
cleared under 510(k) number **K103184** at November 10th, 2010.

DEVICE DESCRIPTION

The sensiLight devices are pulsed light hair removal device. Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. The sensiLight devices are composed of a hand held applicator and an external power supply. The spot size (treatment area) in the sensiLight devices is 3 cm^2.

The device contains a lamp, a skin proximity sensor and a skin pigmentation sensor to detect appropriate skin tones. If the sensiLight is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the sensiLight will not trigger a pulse.

(*) The sensiLight Plus model contains in addition, a movement sensor to prevent pulse overlapping.

Body contact materials were evaluated for biocompatibility with accordance to *FDA's Memorandum – #G95 1, May 1, 1995* and *ISO 10993-1:2009.*

4. INTENDED USE

The sensiLight is an over the counter devices intended for the removal of unwanted hair. The sensiLight is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.

5. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Table 1 presented in the next pages, compares the similarities and differences of EL Global Trade Ltd.'s *sensiLight* device to the predicate devices manufactured by Home Skinovations Ltd. as identified above.

Feature	EL Global Trade Ltd. *sensiLight & sensiLight Plus* -New Devices -	Home Skinovations Ltd. *Glide* 510(k) no. K131870	Home Skinovations Ltd. *Silk'n Flash N Go* 510(k) no. K103184
Intend of use	The sensiLight is an over the counter device intended for the removal of unwanted hair. The sensiLight is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regime.	The Glide™ device is an over the counter device intended for the removal of unwanted hair. The Glide™ device is also intended for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.
Operation Principle	Photothermolysis. Light energy is absorbed, heats the hair follicles and interrupts the growth cycle.	Photothermolysis. Light energy is absorbed, heats the hair follicles and interrupts the growth cycle.	Photothermolysis. Light energy is absorbed, heats the hair follicles and interrupts the growth cycle.
Technology	Home Pulsed Light	Home Pulsed Light	Home Pulsed Light
Comparison of treatment regime	• The 1–4 treatments will be approximately two weeks apart • Followed by 5-7 treatments plan four-week time intervals. • Maintenance will be needed from time to time if growth is still visible	• Treatments 1-4 – plan two weeks apart • Treatment 5-7 – plan four weeks apart • Treatment 8+ - treat as needed, until desired results are achieved. Maintenance – from time to time some upkeep may be needed if growth is still visible.	• First 3-4 hair removal sessions will be approximately two weeks apart. • Sessions 5-7 will be approximately four weeks apart. • After, use again from time to time if and when needed, until long-term results are achieved.
Safety	oIEC 60601-1:2005/EN 60601-1:2006. Medical electric equipment-Part 1 General requirements for Basic safety and essential performance, 3rd Ed.	oIEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991 -11, Amendment 2,	oIEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988 (Second Edition).

Feature	EL Global Trade Ltd. *sensiLight & sensiLight Plus* -New Devices -	Home Skinovations Ltd. *Glide* 510(k) no. K131870	Home Skinovations Ltd. *Silk'n Flash N Go* 510(k) no. K103184
	o IEC 60601-1-11:2010. Medical electric equipment-Part 1: Collateral requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. o IEC 60601-2-57:2011. Medical electrical equipment-Part 2: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetics/aesthetic use o IEC 62471:2006 (First Edition) Photo-biological safety of lamps and lamp systems	1995. o EN 6060 1-2-57: 2011 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmeti c/aesthetic use. o EN 62471: 2008 Photobiological safety of lamps and lamp systems.	
EMC	IEC 60601-1-2:2013 (Medical electrical equipment –fourth Edition). Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	IEC 60601-1-2 (2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests	IEC 60601-1-2 (2004), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
Performance Features			
Optical aperture	3 [cm^2]	2. 7 [cm^2]	6 [cm^2]
Emitted Spectrum	475-1200 [nm]	475-1200 [nm]	475-1200 [nm]
Max energy level	5 [joules/cm^2]	5 [joules/cm^2]	5 [joules/cm^2]

Feature	EL Global Trade Ltd. *sensiLight & sensiLight Plus* -New Devices -	Home Skinovations Ltd. *Glide* 510(k) no. K131870	Home Skinovations Ltd. *Silk'n Flash N Go* 510(k) no. K103184
(fluence)			
User selectable Energy levels	3	5	5
Single pulse duration	500-800 [uSec]	500-800 [uSec]	500-800 [uSec]
Interval between pulses	~2 [Sec]	1-3.4 [Sec], depending on energy level	~ 3.5 [Sec]
Power Supply	External power supply 110-240 VAC, 50-60Hz to 19VDC, 1.8Amp	External power supply 110-240 VAC, 2Amp	110-240 [VAC], 50-60 [Hz]
Safety Features			
Close contact detector	Prevent the activation of the device while not in close contact with the skin.	Yes	Yes
Pigmentation level detector	Optical – does not allow activation on dark skin	Optical – does not allow activation on dark skin	Optical – does not allow activation on dark skin
(*) Movement sensor	In the sensiLight Plus (Second model)	No	No
Darkest skin allowed	Fitzpatrick 4	Fitzpatrick 4	Fitzpatrick 4
Materials	o Top, Side and Bottom shell - ABS/PC plastic (Acrylonitrile butadiene styrene/PolyCarbonate) o Optical Filter - Color glass which purpose is of an optical long pass filter tested for biocompatibility	o Device outer body - ABS/PC plastic (Acrylonitrile butadiene styrene/PolyCarbonate) o Optical Filter - Color glass which purpose is of an optical long pass filter tested for biocompatibility	o Device outer body - ABS/PC plastic (Acrylonitrile butadiene styrene/PolyCarbonate) o Optical Filter - Color glass which purpose is of an optical long pass filter tested for biocompatibility
Overall Design	The sensiLight device is light based hair removal system composed of a hand-held applicator.	The Glide device is light based hair removal system composed of a hand held applicator.	The Flash N Go is light based hair removal system composed o f a base unit and hand-held applicator.

Feature	EL Global Trade Ltd. *sensiLight & sensiLight Plus* -New Devices -	Home Skinovations Ltd. *Glide* 510(k) no. K131870	Home Skinovations Ltd. *Silk'n Flash N Go* 510(k) no. K103184
Use Environment	Home Use	Home Use	Home Use

The sensiLight device relies on the same technology: Intense Pulsed Light (IPL) which is the same as both predicate devices. The safety and efficacy of IPL treatment for hair reduction are governed by the following parameters:

- Wavelength of the light emitted: Defines the interaction with specific chromophores (the part of the molecule responsible for its color) such as melanin, hemoglobin and water. The sensiLight device and the predicate devices utilize exactly the same wavelength (475 – 1200nm).
- Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. The sensiLight device and the predicate devices deliver exactly the same maximum energy (5 joules/cm^2).
- Pulse duration – Provides for an efficient heating of the target molecule but not its surroundings. The sensiLight device and the predicate devices utilize exactly the same pulse.

6. PERFORMANCE DATA

EL Global Trade Ltd's *sensiLight* has been successfully tested through bench, usability and safety tests to support the determination of substantial equivalence with predicate devices.

The sensiLight device has been tested and complies with the following voluntary recognized standards:

1. IEC 60601-1:2005/EN 60601-1:2006. *Medical electric equipment-Part 1 General requirements for Basic safety and essential performance, 3rd Ed.*
2. IEC 60601-1-11:2010. *Medical electric equipment-Part 1: Collateral requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*
3. IEC 60601-2-57:2011. *Medical electrical equipment-Part 2: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetics/aesthetic use.*

4. IEC 60601-1-11. *Medical electric equipment-Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*
5. FCC part 15, Subpart B, Class B.
6. IEC 60601-1-2:2007 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*
7. Software Validation was conducted according to IEC 62304:2006 - *Medical device software - Software life cycle processes,* and;
   FDA Guidance for the *Content of Pre-Market Submissions for Software Contained in Medical Devices*, dated May 11, 2005.
8. ISO 10993-1:2009 – *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and with FDA's Memorandum – *#G95 1, May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* (Blue Book Memo G95-1).
9. IEC 60601-1-6:2010, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance* and IEC 62366:2007 – *Medical devices – Application of usability engineering to medical devices - Collateral standard: Usability* and FDA Guidance for Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (July18,2000) and ISO/IEC 14971:2007 (BS EN ISO 14971:2012) Medical devices – Application of risk management to medical devices.
10. IEC 62471:2006, *Photo-biological safety of lamps and lamp systems*.

Tests results are supporting all labeling claims in order to establish substantial equivalency.

7. SUBSTANTIAL EQUIVALENCE

EL Global Trade Ltd.'s *sensiLight* is substantial equivalent to the predicate device selected in terms of indication for use, technology, performances, place of use, patient population and nature of body contact.

The Substantial equivalent decision was received based on the following comparison with the predicate device:

The design and components in the sensiLight, including the hand held applicator (with lamp, microcontroller, fan, skin color sensor, skin proximity sensor, indicator LEDs and operational button/s) are similar to the design and components found in the predicate devices (K131870 and K103184). The performance specifications (including light energy

power, wavelength and pulse duration) are identical. The safety features found in the devices are the same, including the skin color sensor, skin proximity sensor, etc. These safety features in the sensiLight device are substantially equivalent to the safety features found in the predicate devices. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new sensiLight device underwent performance testing, including software validation testing and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2. Usability testing was also successfully conducted.

8. CONCLUSIONS

The evaluation of our device performances demonstrates that it is as safe and as effective as the predicate devices.